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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,151	05/18/2006	George C. Prendergast	3882-P03161US2	4302

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
STONE, CHRISTOPHER R	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,151	PRENDERGAST ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *1-37,40 and 48-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 39, 41-47 and 53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/30/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed July 30, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-56 are pending. Claims 1-37, 40, 48-52 are withdrawn from consideration. Claims 38, 39, 41-47 and 53-56 are under examination. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38, 39, 41-47 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munn et al (US PGPUB 2001/0001040) in view of Hausheer et al (US 5,902,610)

Claims 38, 39, 41-47 and 54-56 are drawn to a method of treating cancer comprising administering an IDO inhibitor and a chemotherapeutic agent. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Munn et al teaches that IDO inhibitors, including 1MT, are useful in the treatment of cancer (paragraph [0017]). Munn et al does not teach the administration of cisplatin with 1MT. Hausheer et al teaches that cisplatin is a widely used anticancer agent used in combination with other anticancer agents in the treatment of a broad spectrum of cancers, including e.g. breast, lung, head and neck, ovary, etc. (column 3, lines 32-39). Hausheer et al further teaches that additional anticancer agents can be administered prior to, simultaneously or following the administration of cisplatin in combination therapies (column 1, lines 11-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to administer 1MT and cisplatin, concurrently or sequentially, in any order, to treat cancers, including breast, lung, head and neck, ovary, etc., since both compounds were known to be useful chemotherapeutic agents, thus resulting in the instantly claimed invention with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38, 39, 43-47 55 and 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35 and 36 of copending Application No. 10550444 in view of Munn et al (US PGPUB 2001/0001040) and Hausheer et al (US 5,902,610)

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 35 and 36 of copending Application No. 10550444 are drawn to a composition comprising an IDO inhibitor and an anticancer agent, including cisplatin; however claims 35 and 36 of copending Application No. 10550444 are not expressly drawn to a method of treating cancer comprising administering said composition. Munn et al teaches that IDO inhibitors are useful in the treatment of cancer

(paragraph [0017]). Hausheer et al teaches that cisplatin is a widely used anticancer agent used in combination with other anticancer agents in the treatment of a broad spectrum of cancers, including e.g. breast, lung, head and neck, ovary, etc. (column 3, lines 32-39). Hausheer et al further teaches that additional anticancer agents can be administered prior to, simultaneously or following the administration of cisplatin in combination therapies (column 1, lines 11-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to administer an IDO inhibitor and cisplatin (i.e. the composition of claims 35 and 36 of copending Application No. 10550444), concurrently or sequentially, in any order, to treat cancers, including breast, lung, head and neck, ovary, etc., since both compounds were known to be useful chemotherapeutic agents, thus resulting in the instantly claimed invention with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

With regard to Applicant's allegations of unexpected results, Applicant is reminded that a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case greater than additive

anti-tumor effect of the instantly examined elected species of IDO inhibitor and chemotherapeutic agent are not unexpected since IDO inhibitors were known to have chemosensitizing activity (see e.g. Sabol et al, Biologia, Bratislava, 55(6), p. 701-707, 2000, p. 702, last paragraph left column to first paragraph right column). That is one of ordinary skill in the art at the time of the instantly claimed invention would have reasonably expected the instantly claimed combination to have greater than additive cancer growth inhibition due to the known chemosensitizing activity of IDO inhibitors.

Facts and Evidence

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sabol et al, Biologia, Bratislava, 55(6), p. 701-707, 2000.

This reference is cited to demonstrate the known chemosensitizing activity of IDO inhibitors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642